

In the United States Court of Federal Claims

No. 98-916V

(Filed: August 6, 2009)<sup>1</sup>

THERESA and MICHAEL CEDILLO,  
as Parents and Natural Guardians of  
MICHELLE CEDILLO,

## Petitioners,

V.

SECRETARY OF HEALTH AND  
HUMAN SERVICES,

### Respondent.

\* Vaccine Act; Omnibus Autism Proceeding; Effect of Thimerosal and Measles, Mumps, and Rubella Vaccine in Causing Autism; Burden of Proof; Standard of Review; Analysis of Causation-in-Fact Evidence; Assessment of Expert Testimony.

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## OPINION AND ORDER

WHEELER, Judge.

This case is before the Court for review of the Special Master's February 12, 2009 decision dismissing Theresa and Michael Cedillo's petition for compensation under the

<sup>1</sup> During the July 7, 2009 oral argument in this case, counsel for the parties waived the usual 14-day period under Rules of the United States Court of Federal Claims (“RCFC”), Appendix B, Vaccine Rule 18(b) to review the decision for confidential or privileged information. Accordingly, the Court is releasing the entire decision for publication this day.

National Childhood Vaccine Injury Act of 1986, 42 U.S.C. § 300aa-1 *et seq.* (2006) (the “Vaccine Act”). See Cedillo v. Sec'y of HHS, No. 98-916V, 2009 WL 331968, at \*1 (Fed. Cl. Spec. Mstr. Feb. 12, 2009) (hereinafter “Cedillo”). Petitioners assert that their daughter, Michelle Cedillo, suffered severe autism and gastrointestinal injuries from various vaccines containing thimerosal, and from the measles, mumps and rubella (“MMR”) vaccine. This case was the first of three test cases under the Office of Special Masters’ Omnibus Autism Proceeding established in July 2002 to assist in the resolution of approximately 5,000 autism cases pending in this Court. The other two test cases, also decided by Special Masters on February 12, 2009, are Snyder v. Secretary of Health & Human Services, No. 01-162V, 2009 WL 332044 (Fed. Cl. Spec. Mstr. Feb. 12, 2009) and Hazlehurst v. Secretary of Health & Human Services, No. 03-654V, 2009 WL 332258 (Fed. Cl. Spec. Mstr. Feb. 12, 2009), *aff'd* No. 03-654V, 2009 WL 2371336 (Fed. Cl. July 24, 2009).

In brief summary, Petitioners argue that Michelle Cedillo was a normal child for her first sixteen months until she experienced the effects of eleven vaccinations containing thimerosal, and the MMR vaccination. Pet'r Br. 2, 17 n.41, Mar. 16, 2009. Thimerosal is a compound consisting of mercury and other components that has been used since the 1930s in very small amounts as a preservative in vaccines to prevent fungal and bacterial contamination. Cedillo, at \*17. The Cedillos claim that the ethyl mercury in thimerosal and the MMR vaccine damaged their daughter’s immune system, and that due to her immune deficiency, she was unable to clear from her body the measles virus contained in the MMR vaccine. Instead, the measles virus persisted and replicated in Michelle’s body, causing her to suffer inflammatory bowel disease. The Cedillos also contend that the measles virus ultimately entered Michelle’s brain, causing inflammation and autism.

In a 174-page decision, Special Master George Hastings rejected all of Petitioners’ contentions, observing that “the evidence was overwhelmingly contrary” to the Cedillos’ claims. Id. at \*1. Regarding some 23 expert witnesses who testified or submitted reports, he stated that “[t]he expert witnesses presented by the respondent were far better qualified, far more experienced, and far more persuasive than the petitioners’ experts, concerning most of the key points.” Id. While acknowledging that Michelle Cedillo “has tragically suffered from autism and other severe conditions,” the Special Master concluded, “the petitioners have . . . failed to demonstrate that [Michelle’s] vaccinations played any role at all in causing those problems.” Id.

Petitioners timely filed their motion for review on March 16, 2009, raising seven arguments to support their position that the Special Master’s decision is arbitrary, capricious, and not in accordance with law. Respondent filed a response memorandum on April 15, 2009, and the Court heard oral argument on July 7, 2009. Like the Special Master, the Court expresses its deep sympathy and admiration for the Cedillo family in caring for Michelle, and

for the countless other families who deal with autism on a daily basis. However, for the reasons explained in detail below, the Court finds that Petitioners' arguments linking Michelle Cedillo's injuries to thimerosal and the MMR vaccine are without merit. Accordingly, the Court affirms the Special Master's February 12, 2009 decision.

#### Factual Background

Michelle Cedillo was born on August 30, 1994. Id. at \*4. Mrs. Cedillo's pregnancy and Michelle's birth were uncomplicated. Id. Records from Michelle's visits to pediatricians during her first sixteen months indicate relatively normal health. Id. She experienced a few typical childhood ailments, such as an episode of vomiting and loose stools in March 1995, and constipation in June 1995. Id. At two months of age, she was able to fix her eyes and follow a moving object, and to become startled in response to a loud noise. Id. At one year, she spoke a few words, crawled on her knees, and pulled herself to stand. Id. She began walking at sixteen to eighteen months, although the record lacks precision on this point. See Transcript of Proceedings, 1332-33, June 11-26, 2007 ("Tr."); Ex. 28 at 207.

Michelle received two early hepatitis B vaccinations, one in the hospital shortly after her birth, and the second on September 27, 1994. Cedillo, at \*4. She received a diphtheria/tetanus/pertussis ("DTP") vaccination on October 31, 1994, a hemophilus influenza vaccination on December 27, 1994, and a polio vaccination on March 8, 1995. Id. She also received a third hepatitis B vaccination on March 8, 1995. Id. She received a chicken-pox vaccination on September 6, 1995. Id. The DTP, hepatitis B, and hemophilus influenza vaccines all contained a small amount of thimerosal. Id.

On December 20, 1995, at fifteen months of age, Michelle received an MMR vaccination at the office of her pediatrician, Dr. Daniel Crawford, of Yuma Pediatrics. Id.; Ex. 8 at 2. She next visited her pediatrician on January 6, 1996. Cedillo, at \*5. On that visit, Mrs. Cedillo reported to Dr. Crawford that, one week after the MMR vaccination, Michelle had developed a fever and rash. Id. Although the fever subsided, it spiked again on January 5, 1996 and was accompanied by a cough and "gagging to the point of vomiting." Id. On the morning of January 6, 1996, Michelle's temperature, taken at home, was 105.7 degrees. Id. Dr. Crawford later recorded her temperature as 100.3 degrees and noted that Michelle was crying and had a "purulent postnasal drip." Id. Dr. Crawford diagnosed her with "sinusitis vs. flu" and prescribed antibiotics. Id.

Michelle visited Yuma Pediatrics again on March 15, 1996 for her scheduled well-child check-up at age eighteen months. Id.; Ex. 8 at 1. Her medical records from this visit do not reflect any significant problems, stating that she seemed to "hear well" and "stool[] well." Cedillo, at \*5. However, Dr. Crawford noted that Michelle was "talking less since

ill in [January].” Id. At this visit, Michelle received additional DTP and hemophilus influenza vaccinations, both of which contained thimerosal. Pet’r Br. 17. Michelle did not see a physician again for more than one year. Cedillo, at \*5.

On April 24, 1997, Michelle visited another pediatrician, Dr. Emilia Matos, whose notes indicate that a “developmental delay [is] suspected” and that she was referring Michelle to a specialist for further evaluation. Id. On May 2, 1997, Dr. William Masland, a neurologist, noted in Michelle’s medical history that at sixteen months, she had developed a fever of over 105 degrees two weeks after the MMR immunization and lasting four days. Id. He added, “[s]ince then she [had] lost her ability to verbalize” and concluded, “[i]t would appear that there was some neurological harm done at the time of the fevers. Whether this was a post-immunization phenomenon or a separate occurrence, would be very difficult to say.” Id.

Following these doctors’ visits in early 1997, medical records show that Michelle’s development became quite abnormal. Id. On July 21, 1997, Dr. Karlsson Roth, a developmental psychologist, examined Michelle and diagnosed her with severe autism and profound mental retardation, concluding that her future potential would be “extremely limited.” Id. Michelle’s evaluations in later years confirmed these diagnoses. For example, on March 1, 1999, Dr. Ira Lott, a pediatric neurologist, determined that Michelle had “autism of a severe degree” and that she “[did] not have much in the way of communicative speech.” Id.

In addition to her severe autism and mental retardation, Michelle has suffered significant gastrointestinal problems. Id. at \*6. Medical records indicate that Michelle began experiencing chronic diarrhea in May 1999. Id. She also suffered symptoms in 2000 suggesting gastroesophageal reflux disease, erosive esophagitis, and fecal impaction. Id. Beginning in June 2000, Michelle underwent multiple upper and lower endoscopies. Id. at \*6, 116.<sup>2</sup> During one such procedure in January 2002, a tissue sample was taken from Michelle’s intestine. Id. at \*6. The Unigenetics Laboratory in Dublin, Ireland performed a “Measles Virus Detection” test on this tissue sample, and concluded in a March 15, 2002 report that “measles virus was detected” in the tissue. Id. However, as will be addressed below, Special Master Hastings determined that the Unigenetics test results were unreliable. Id. at \*30, 46, 58-59.

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<sup>2</sup> An upper endoscopy is performed by inserting a tube into the mouth, down the esophagus, into the stomach and the first part of the small intestine. Tr. 2096. A lower endoscopy, also called a colonoscopy, is performed by inserting a tube into the rectum, through the large intestine and into the bottom of the small intestine, an area referred to as the terminal, the end of the ileum. Id. at 2096-97A. The inserted tubes take pictures of the gastrointestinal tract, permitting a diagnostic evaluation.

Michelle also has experienced arthritis, uveitis (inflammation of the eyes), pancreatitis, and severe feeding problems, requiring the use of a feeding tube. Id. at \*6, 122. In more recent years, she has suffered from a severe seizure disorder, resulting once in a fractured leg when she fell. Id. at \*6. The Special Master rightly observed that Michelle Cedillo continually has “suffered from a tragic series of medical misfortunes.” Id.

### History of Proceedings

Petitioners Theresa and Michael Cedillo filed their claim for compensation under the Vaccine Act on December 9, 1998. Id. at \*13. Initially, the Cedillos asserted that Michelle’s MMR vaccine caused her to suffer an encephalopathy, which is a “Table Injury” under the Vaccine Act. Id.; Resp’t Br. 2, Apr. 15, 2009. For a “Table Injury,” the claimant must show that he or she received a vaccination listed on the Vaccine Injury Table, and suffered a listed injury within a prescribed period. Upon such a showing, the vaccine is presumed to have caused the injury, entitling the petitioner to compensation unless the respondent shows that the injury was caused by some other factor. 42 U.S.C. § 300aa-14; Pafford v. Sec’y of HHS, 451 F.3d 1352, 1355 (Fed. Cir. 2006) (citation omitted).

On January 14, 2002, the Cedillos changed their petition from a “Table Injury” claim to a “causation-in-fact” claim. Cedillo, at \*13. Under the amended petition, the Cedillos alleged that vaccines containing thimerosal, in combination with the MMR vaccine, cause autism. Id. at \*15. A “causation-in-fact” claim does not carry a presumption of causation, and places the burden on the petitioner to prove that the vaccination actually caused the injury in question. Capizzano v. Sec’y of HHS, 440 F.3d 1317, 1320 (Fed. Cir. 2006) (citations omitted).

Michelle Cedillo’s case is one of approximately 5,000 Vaccine Act cases pending in this Court alleging that a child’s autism or similar disorder was caused by one or more vaccines. Cedillo, at \*7. The term “autism” describes a set of developmental disorders characterized by impairments in social interaction, impairments in verbal and non-verbal communication, and restricted or repetitive patterns of behavior. Id. On July 3, 2002, in an effort to manage this large group of autism cases, the Chief Special Master instituted an Omnibus Autism Proceeding (“OAP”). Id. at \*8. Under the OAP procedures, a group of counsel known as the Petitioners’ Steering Committee (“PSC”), selected from the attorneys representing petitioners in the autism cases, had the responsibility for developing and presenting evidence on the general causation issue of whether the vaccines in question could cause autism. Id. The Special Masters then would apply the PSC’s evidence to individual cases. Id.

The Chief Special Master initially designated Special Master Hastings to preside over the OAP, and to resolve individual petitions alleging that vaccines or thimerosal cause autism. Id. at \*9. On January 11, 2007, the Chief Special Master named two additional Special Masters, Denise Vowell and Patricia Campbell-Smith, to preside jointly with Special Master Hastings over the OAP. Id. The individual petitions were divided among these three Special Masters. Id. A petitioner could elect to opt out of the OAP at any time if he or she did not want to await the outcome of the general causation proceedings. Id. at \*9 n.14.

From 2002 to 2006, the PSC engaged in discovery on the general causation issue. Id. at \*9. On December 20, 2006 and again on January 9, 2007, the PSC proposed that the general causation evidence be divided among three separate theories: (1) the combination of the MMR vaccine and thimerosal-containing vaccines can cause autism; (2) thimerosal-containing vaccines alone can cause autism; and (3) the MMR vaccine alone can cause autism. Id. The PSC proposed using Michelle Cedillo as a test case in June 2007 to present the first general causation theory. Id. The three Special Masters agreed to the PSC's proposal but directed the PSC to select two additional test cases falling within the same general causation theory. Id. at \*10. Under this plan, the PSC would present its general causation evidence concerning the first theory, along with evidence specific to Michelle Cedillo's case, in June 2007, after which the PSC would present the specific evidence for the two additional test cases. Id. Thereafter, the Special Masters would use a similar approach for each of the other two general causation theories. Id.

The parties submitted a vast amount of evidence in the Cedillo case on the general causation theory that the MMR vaccine and thimerosal-containing vaccines can combine to cause autism. Id. Special Master Hastings conducted an evidentiary hearing in the Cedillo case during June 11–26, 2007 to hear both general causation evidence and evidence specific to Michelle Cedillo's case. Id.; Tr. 1-2917. Petitioners presented testimony from six expert witnesses: H. Vasken Aposhian, Ph.D. (toxicology); Vera Byers, M.D., Ph.D. (immunology); Karin Hepner, Ph.D. (molecular biology); Ronald Kennedy, Ph.D. (virology); Marcel Kinsbourne, M.D. (neurology); and Arthur Krigsman, M.D. (gastroenterology). Tr. 3, 301, 578A, 861, 1026. Petitioners also called Theresa Cedillo, Michelle's mother, to testify as a fact witness. Id. at 3, 301, 2874. Respondent presented testimony from nine expert witnesses: Jeffrey Brent, M.D., Ph.D. (toxicology); Stephen Bustin, Ph.D. (molecular biology); Edwin Cook, M.D. (psychiatry, genetics); Eric Fombonne, M.D., FRCPsych (pediatric psychiatry, epidemiology); Diane Griffin, M.D., Ph.D. (virology); Stephen Hanauer, M.D. (gastroenterology); Christine McCusker, M.D. M.Sc., FRCP (pediatric immunology); Brian Ward, M.D., M.Sc. (virology); and Max Wiznitzer, M.D. (pediatric neurology). Id. at 1216, 1560, 1793, 2074, 2280, 2498. Respondent also submitted expert reports from Robert Fujinami, Ph.D. (immunology), Michael Gershon, M.D. (neurogastroenterology), and Andrew Zimmerman, M.D. (pediatric neurology), but these

experts did not testify. Resp't Br. 4. Nicholas Chadwick, Ph.D. testified as a fact witness for Respondent. Tr. 2280. Special Masters Vowell and Campbell-Smith heard all of the testimony in Cedillo so that they could apply the general causation evidence to the individual test cases assigned to them. Cedillo, at \*10.

Special Master Campbell-Smith conducted an evidentiary hearing in Hazlehurst during October 15–18, 2007, and Special Master Vowell conducted an evidentiary hearing in Snyder during November 5–9, 2007. Id. at \*11. All three of the Special Masters attended these hearings. Id. In both Hazlehurst and Snyder, Special Master Hastings permitted the Cedillo Petitioners to submit additional general causation evidence, and Respondent to submit additional rebuttal evidence. Id. at \*14. The parties filed extensive post-hearing briefs between November 2007 and February 2008, and Special Master Hastings closed the evidentiary record on July 30, 2008. Id. at \*11, 14.

The evidentiary record in these cases easily is the largest of all cases presented to the Court in the history of the Vaccine Act. Michelle Cedillo's medical records alone comprise some 7,700 pages. Id. at \*14. The parties filed 23 expert reports in Cedillo, and 50 expert reports in Hazlehurst and Snyder combined. Id. Fifteen expert witnesses testified in Cedillo, four in Hazlehurst, and eight in Snyder. Id. The hearing transcripts consist of 2,917 pages in Cedillo, 1,049 pages in Snyder, and 570 pages in Hazlehurst. Id. The record in the three cases also contains 939 medical journal articles, textbook excerpts, and other medical literature. Id. These materials, perhaps daunting even to medical professionals, relate to the subjects of neurology, gastroenterology, virology, immunology, molecular biology, toxicology, genetics, and epidemiology. Id. at \*15.

On February 12, 2009, Special Master Hastings issued his decision denying the Cedillos' claim under the Vaccine Act. According to the Special Master, Petitioners failed to demonstrate that: (1) thimerosal-containing vaccines can harm infant immune systems in general, or that Michelle Cedillo's own thimerosal-containing vaccinations harmed her immune system; (2) the MMR vaccine can cause autism in general, or that Michelle Cedillo's own MMR vaccination contributed to her autism; (3) the MMR vaccine can cause gastrointestinal dysfunction in general, or that Michelle Cedillo's own MMR vaccination contributed to her gastrointestinal problems; or (4) Michelle Cedillo's own MMR vaccination caused her mental retardation or seizure disorder. Id. Furthermore, the Special Master deemed unreliable the testing Petitioners offered to show the presence of the measles virus in Michelle Cedillo and other autistic children. Id. The Special Master also found that the evidence concerning the causation of regressive autism combined with gastrointestinal dysfunction in some individuals did not persuasively show either or both conditions to be vaccine-related. Id.

On March 13, 2009, Petitioners filed a motion for reconsideration, requesting the Special Master to overturn his February 12, 2009 decision based on new evidence not available at the June 2007 hearing. Special Master Hastings denied the motion on March 16, 2009 because it was not filed within the 21-day period required by RCFC, Appendix B, Vaccine Rule 10(e). Cedillo v. Sec'y of HHS, No. 98-916V, 2009 WL 996299, at \*1 (Fed. Cl. Spec. Mstr. Mar. 16, 2009). Even if Petitioners had timely filed their motion, the Special Master concluded that it would not be “in the interest of justice” to withdraw his decision. Id. On that same day, Petitioners filed with the Court their motion for review of the Special Master’s decision.

### Discussion

#### A. Standard of Review

This Court has jurisdiction under the Vaccine Act to review a Special Master’s decision upon the timely request of either party. 42 U.S.C. § 300aa-12(e)(1)-(2). The Special Master’s findings of fact receive deferential review under an “arbitrary and capricious” standard, while the Court reviews legal conclusions under the “not in accordance with law” standard and discretionary rulings for an “abuse of discretion.” Munn v. Sec'y of HHS, 970 F.2d 863, 870 n.10 (Fed. Cir. 1992); see also Lampe v. Sec'y of HHS, 219 F.3d 1357, 1360 (Fed. Cir. 2000); Johnson v. Sec'y of HHS, 33 Fed. Cl. 712, 720 (1995), aff’d, 99 F.3d 1160 (Fed. Cir. 1996) (table). Thus, when the Court is deciding whether a Special Master’s decision should be affirmed or set aside, it must apply a different standard to each aspect of the Special Master’s judgment. See Centmehaiey v. Sec'y of HHS, 32 Fed. Cl. 612, 619 (1995), aff’d 73 F.3d 381 (Fed. Cir. 1995) (table). Combining these standards, this Court “may set aside the decision of a special master only if the special master’s fact findings are arbitrary and capricious, its legal conclusions are not in accordance with law, or its discretionary rulings are an abuse of discretion.” Turner v. Sec'y of HHS, 268 F.3d 1334, 1337 (Fed. Cir. 2001) (citing 42 U.S.C. § 300aa-12(e)(2)(B)). On review, the Vaccine Act empowers the Court to: (1) uphold the findings of fact and conclusions of law and sustain the decision; (2) set aside any findings of fact and conclusions of law “found to be arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law . . .”; or (3) “remand the petition to the special master for further action in accordance with the court’s direction.” 42 U.S.C. § 300aa-12(e)(2)(A)-(C).

#### B. Causation Standard

For a “causation-in-fact” claim under the Vaccine Act, the petitioner has the burden of proving a *prima facie* case by a preponderance of the evidence. 42 U.S.C. § 300aa-

13(a)(1)(A). The petitioner must show the following three criteria to establish that the vaccine caused the injury:

1. A medical theory causally connecting the vaccination and the injury;
2. A logical sequence of cause and effect showing that the vaccination was the reason for the injury; and
3. A proximate temporal relationship between vaccination and injury.

Althen v. Sec'y of HHS, 418 F.3d 1274, 1278 (2005); see also Andreu v. Sec'y of HHS, 569 F.3d 1367, 1374-75 (Fed. Cir. 2009) (citation omitted). If the petitioner satisfies these three elements, the burden then shifts to the respondent to show by a preponderance of the evidence that other factors unrelated to the vaccine caused the injury. See Althen, 418 F.3d at 1278 (citation omitted).

The causation theory advanced by a petitioner must be supported by a reliable scientific or medical explanation. Grant v. Sec'y of HHS, 956 F.2d 1144, 1148 (Fed. Cir. 1992) (citation omitted); see also RCFC, App. B, Vaccine Rule 8(b) (special master must consider all “relevant and reliable” evidence); Knudsen v. Sec'y of HHS, 35 F.3d 543, 548 (Fed. Cir. 1994) (stating that a causation theory before a special master must be supported by a “sound and reliable” medical or scientific explanation) (citation omitted).

### C. Petitioners' Contentions On Review

The Cedillos assert seven arguments in their motion for review to show that the Special Master's decision is arbitrary, capricious, an abuse of discretion, and contrary to law: (1) A panel of three Special Masters should not have heard the general causation evidence; (2) The Special Masters should not have allowed the last-minute expert reports and testimony of Dr. Stephen Bustin; (3) The Special Master improperly discounted the medical diagnoses and opinions of Michelle Cedillo's treating physicians; (4) The Special Master improperly ignored concessions made by Respondent's expert witnesses; (5) The Special Master ignored important aspects of Michelle Cedillo's evidence; (6) The Special Master abused his discretion by refusing to consider important post-hearing evidence; and (7) the Special Master's decision was contrary to law. Petitioners' arguments four and five include multiple sub-parts, specifically raising the testimony of six expert witnesses and seven substantive areas of Petitioners' evidence that the Special Master allegedly mis-evaluated.

In analyzing Petitioners' contentions, the Court first will address the important issue of whether the Special Master properly found the test results of the Unigenetics Laboratory unreliable.<sup>3</sup> This issue cuts across many of Petitioners' arguments on review. Petitioners have said, and the Court agrees, that the reliability of the Unigenetics Laboratory is "the single-most critical issue in the case." Pet'r Br. 30. Two of Petitioners' other arguments, regarding the significance of "high copy" numbers and "allelic discrimination," relate to the testing at the Unigenetics Laboratory, and the Court will discuss them next. The Court then will address the remainder of Petitioners' arguments in the sequence presented in the motion for review.

### 1. The Test Results of the Unigenetics Laboratory

A hotly contested issue in this case is whether the measles virus detection tests performed by the Unigenetics Laboratory in Dublin, Ireland produced reliable results. Petitioners' expert witnesses, Dr. Marcel Kinsbourne and Dr. Arthur Krigsman, acknowledged that their opinion on causation depended upon the existence of a reliable laboratory finding of persistent vaccine-strain measles in the body of the person tested. Cedillo, at \*29, 33, 67. Thus, absent evidence of persistent vaccine-strain measles in Michelle Cedillo's body, Dr. Kinsbourne and Dr. Krigsman cannot show that the MMR vaccine caused Michelle's autism or her inflammatory bowel disease. The Special Master devoted a lengthy section of his decision to this issue, concluding that the Unigenetics test results were not reliable. Id. at \*29-65.

The parties do not dispute the underlying facts relating to the Unigenetics testing. On January 31, 2002, physicians at Samaritan Surgicenters in Phoenix, Arizona performed a biopsy to remove a tissue sample from Michelle Cedillo's small intestine to be tested by the Unigenetics Laboratory. Id. at \*30; Ex. 44 at 13-14. On March 15, 2002, after performing measles detection testing on the tissue sample, the Unigenetics Laboratory reported that "measles virus was detected" in the tissue. Cedillo, at \*30; Ex. 28 at 179. Unigenetics also performed measles detection testing on other persons, and reported the results in an article, V. Uhlmann et al., *Potential Viral Pathogenic Mechanism for New Variant Inflammatory Bowel Disease*, 55 MOLECULAR PATHOLOGY 84 (2002) (the "Uhlmann Study"). Cedillo, at \*30 n.58. One of the co-authors of this article was Dr. Andrew Wakefield, a British physician who had asserted in 1998 that the MMR vaccine can cause autism. Id. The Uhlmann Study concluded that the measles virus was detected in a large majority of the developmentally-disabled children tested, but only in a few of the developmentally-normal

<sup>3</sup> Petitioners refer to the Unigenetics Laboratory as the "O'Leary Lab," but they are the same laboratory. In this decision, the Court will refer to it as the "Unigenetics Laboratory."

children tested. Id. at \*31. The Unigenetics testing of Michelle's tissue sample and the results of the Uhlmann Study are key components of Petitioners' causation-in-fact evidence.

Dr. John O'Leary and his colleagues formed Unigenetics Laboratory Ltd. as a for-profit company to perform testing for the measles virus, principally to provide testing of claimants in British autism litigation. Id. at \*30. Although the general reputations of Unigenetics and Dr. O'Leary are good, id. at \*46, Respondent presented evidence of significant shortcomings in the measles detection work at Unigenetics. For example, Unigenetics was not an accredited laboratory, and it declined to participate in any independent quality control program. Id. at \*36, 47. Respondent's experts observed that after-the-fact alterations had been made in Unigenetics' laboratory notebooks, casting doubt on the credibility of the procedures used. Id. at \*36, 38. Dr. Thomas MacDonald, an expert witness for Respondent in Hazlehurst, testified that the Uhlmann Study was "one of the worst" medical journal articles he has ever seen, that the Molecular Pathology journal is "the worst journal that has ever been seen," and that the journal is "no longer in existence." Id. at \*39. Unigenetics apparently dissolved as a business in 2005, although Dr. O'Leary's Dublin laboratory continues to operate and publish work. Id. at \*32.

From a medical standpoint, Respondent's experts were highly critical of Unigenetics and the Uhlmann Study. The testing method used in the Uhlmann Study is known as polymerase chain reaction ("PCR"). Id. at \*31. Respondent's expert, Dr. Brian Ward, testified that PCR is a sensitive testing technique, and not easy to perform properly. Id. at \*34. Dr. Ward explained that the possibility of contamination is a serious problem in PCR testing, and often can yield false positives. Id. Dr. MacDonald criticized the Unigenetics testing procedures as producing an unacceptably high experimental failure rate, using the wrong technical controls, and claiming positive or negative outcomes on a "subjective or spurious" basis. Id. at \*43.

The Uhlmann Study in 2002 added to the controversy on whether the MMR vaccine might be causing autism, and led some medical experts to question the conclusion that measles virus actually had been detected in the tested children. Accordingly, other researchers undertook separate studies to see if they could replicate the results of the Uhlmann Study. Id. at \*32. Two such studies reported in 2006, known as the Afzal Study and the D'Souza Study, cast serious doubt on the outcome of the Uhlmann Study. Id. In the Afzal Study, the researchers used a number of testing methodologies, but found none of the samples positive for measles virus for any test. Id. Similarly, in the D'Souza Study, the researchers tested the blood cells of 88 children, 54 of them diagnosed with autism spectrum disorders and 34 developmentally-normal children. Id. All but six of the children had received the MMR vaccine. Id. The researchers concluded that none of the studied children had persistent measles virus infection. Id.

The D'Souza research team initially yielded positive findings of measles virus for nearly all of the tested samples, just as the Uhlmann Study had. Id. However, the D'Souza group thereafter subjected the positive samples to additional testing techniques involving analysis of “melting curves” and the size of “amplicons.” Id. The use of these two techniques revealed that all but nine of the initially positive samples were in fact not measles virus. Id. For the nine remaining positive samples, the D'Souza team performed a further procedure known as “sequencing.” Id. at \*33. Described as the “gold standard” for determining whether the material being examined actually is measles virus, id., “sequencing” involves ascertaining the nucleotide order in a particular segment of deoxyribonucleic acid (“DNA”), see Snyder, 2009 WL 332044, at \*109-10. The D'Souza group successfully completed the “sequencing” procedure in seven of the remaining nine positive samples, and all seven turned out not to contain the measles virus. Cedillo, at \*33. Although the material had appeared to be measles virus after the PCR testing, “sequencing” showed that it was instead human genetic material. Id.

The D'Souza group determined that the published results of the Uhlmann Study were “unlikely to be true.” Id. In the D'Souza Study, the authors advanced plausible explanations for the Uhlmann Study’s erroneous conclusion that measles virus had been detected in the tissue samples. Id. Principally, the D'Souza Study found that the “primers” used in the Uhlmann Study were not as “specific” as needed to identify positively measles virus material, as opposed to some other material.<sup>4</sup> Id. The D'Souza group concluded that the Uhlmann Study mistakenly identified human genetic material as measles virus material. Id.

Respondent’s experts noted other serious concerns about the Uhlmann Study and the Unigenetics Laboratory that would cast doubt on their reported results. Id. at \*34-39. Among these were the improper use of “controls.” Id. at \*36. In a laboratory setting, “positive controls” are samples that possess the targeted gene, while “negative controls” are samples that do not possess the targeted gene. Id. During a laboratory’s PCR testing, the positive controls always should test positive, and the negative controls always should test negative. Id. If these results are not obtained, a laboratory’s test procedures are not working properly. Id. At Unigenetics, the laboratory obtained positive results from negative controls for approximately one-third of the testing procedures. Id.

According to Respondent’s experts, another problem with the Unigenetics testing involved “discordant replicates.” Id. at \*37, 38. In testing two samples from the same source, the results should either be positive for both samples or negative for both samples. Id. at \*37. However, Unigenetics revealed instances of one positive and one negative test

<sup>4</sup> “Primers” are short pieces of DNA or ribonucleic acid (“RNA”) used in PCR testing. Tr. 593A; 1942A.

from the same source. Id. In such circumstances, Unigenetics should have retested the samples, but it reported the flawed result as a positive test instead. Id. One expert observed that the Unigenetics practice of simply ignoring the negative test “is a wholly unscientific practice and indicates bias in the interpretation of these results.” Id. at \*38.

Respondent’s experts concluded that the Unigenetics test results were unreliable. Dr. Ward testified that he could place no reliance on the work of the Unigenetics Laboratory. Id. at \*35. Dr. Bustin determined that Unigenetics erroneously detected a DNA contaminant, and did not detect the measles virus. Id. at \*37. He opined, “I do not believe there is any measles virus in any of the cases they have looked at.” Id. Dr. Bertus Rima, an expert for Respondent who testified in Snyder, stated that the Unigenetics testing “simply does not work,” meaning that such testing is not able to detect reliably whether measles virus is present. Id. at \*38.

As noted above, Petitioners’ experts, Dr. Kinsbourne and Dr. Krigsman, relied upon the Unigenetics test results in concluding that the MMR vaccine causes autism, but they could not opine on the validity of the testing. Petitioners presented two other experts, Dr. Karin Hepner and Dr. Ronald Kennedy, who thought that the Unigenetics test results were reliable. Id. at \*33-34. Dr. Hepner attempted to distinguish the 2006 Afzal and D’Souza studies, pointing out that the researchers tested blood cells of the children in those tests, not intestinal material. Id. at \*33. Dr. Kennedy testified about a meeting that he and other scientists attended with Dr. Orla Sheils, a colleague of Dr. O’Leary. Id. at \*34. Dr. Kennedy and the other scientists asked many questions of Dr. Sheils regarding the Unigenetics testing procedures. Id. Dr. Kennedy formed the impression that the testing was valid. Id.

Weighing all of the evidence, the Special Master concluded that the Unigenetics testing for the detection of measles virus was not reliable. Id. at \*39. The Special Master emphasized that other researchers had been unable to replicate the Unigenetics findings. Id. at \*40-41. He found it significant that Unigenetics had failed to employ “sequencing” in its testing procedures. Id. at \*41-43. He was troubled by the many problems with Unigenetics’ procedures, facilities, and equipment. Id. at \*43-45. Among these were the failure to employ “blinding” procedures so that the laboratory technicians would not know whether the samples being tested were from the patient group of interest. Id. at \*43. These procedures are regarded as “critical” to prevent conscious or subconscious bias from affecting test results. Id. The Special Master found the efforts of Dr. Hepner and Dr. Kennedy to defend the Unigenetics work largely ineffective. Id. at \*44. Their testimony was “too summary and nonspecific to answer the criticisms leveled by Drs. Bustin and Rima, which were specific and detailed.” Id. Moreover, even the Unigenetics’ test results failed to identify any vaccine-strain measles, which would have been critical to linking the MMR vaccine to autism or inflammatory bowel disease. Id. at \*51-53. Petitioners needed to show that the measles virus

allegedly detected in Michelle's tissue sample derived from the MMR vaccine, rather than the natural, "wild" form of measles virus, but they did not. Id. at \*51. On balance, the Special Master concluded that Respondent's experts, Drs. Ward, Bustin, Rima, and MacDonald, had "vastly more experience and academic credentials" than Petitioners' expert, Dr. Hepner, and that Dr. Bustin's PCR experience and Dr. Rima's measles virus experience far exceeded Dr. Kennedy's. Id. at \*58.

The Court performed a detailed review of the record and the Special Master's analysis of the Unigenetics testing. The Court agrees with the Special Master that the evidence strongly favors Respondent's position. Aside from the superior qualifications and experience of Respondent's experts, the Court finds the results of the 2006 Afzal and D'Souza studies to be most compelling. The researchers in those studies sought to replicate the Uhlmann Study upon which Petitioners so heavily rely. Not only did the Afzal and D'Souza researchers fail to replicate the results of the Uhlmann Study, they came to a conclusion directly opposite to the Uhlmann Study, and they offered likely reasons to explain how the Uhlmann Study had gone astray. The Court also finds that the flaws in the Unigenetics Laboratory procedures were so pervasive that the test results simply cannot be trusted.

Without the test results of the Unigenetics Laboratory, Petitioners have lost a cornerstone to their causation theory. The fact that Petitioners did not prove the existence of any persistent vaccine-strain measles in Michelle Cedillo's body leaves Petitioners well short of meeting their *prima facie* case that the MMR vaccine played any role in causing Michelle's autism. Under these circumstances, Petitioners failed to meet their burden of proof by a preponderance of the evidence, and thus the burden never shifted to Respondent to rebut Petitioners' proof. See Althen, 418 F.3d at 1278. The Special Master's decision regarding the Uhlmann Study and the Unigenetics testing is reasonable in all respects, and could not in any sense be regarded as arbitrary, capricious, or an abuse of discretion.

## 2. The Significance of "High Copy Numbers"

Petitioners argue that, even if the reliability of the Unigenetics' testing procedures is subject to question, the test results should be accepted as accurate when the presence of the measles virus is high. See Pet'r Br. 45-49. Respondent has explained that, in PCR testing, a "copy number" is the reported amount of measles virus in a given sample. Resp't Br. 35 n.24. Respondent's expert, Dr. Rima, testified that the "copy number" in a PCR test is the ratio between the number of actual copies found of the target, such as the F-gene of the measles virus, and the number of copies found of a "housekeeping gene," present in all cells of the body. Cedillo, at \*50. Thus, the ratio of the measles gene to the housekeeping gene is the number that has significance. Id. When Unigenetics reported a "high copy number" of detected measles virus, it did not necessarily mean that a large amount of measles virus

had been found, or that a “high copy number” meant that the tests should be considered reliable. Id. at \*50-51.

Dr. Rima further explained that even “high copy numbers” can be the result of contamination. Id. at \*51. The extremely high copy numbers for some samples, such as for Michelle Cedillo, were so high as to be “completely and utterly biologically implausible” on their face. Id. Dr. Rima stated that if the cells in those samples really had within them as many copies of the measles virus F-gene as reported, they would be so “stuffed” with the measles virus F-gene alone that there would be no room in the cells for the other necessary cell components, such as the housekeeping gene. Id. Respondent’s expert, Dr. Ward, agreed with Dr. Rima’s assessment. Id. According to the Special Master, the Petitioners did not reply to this argument. Id.

The Special Master devoted a separate section of his decision to the “high copy numbers” issue, finding that even where Unigenetics had detected a large amount of measles virus, he still could not deem the Unigenetics testing procedures accurate. Id. at \*50-51. The Special Master relied upon Dr. Bustin’s testimony that the testing could not be trusted just because Unigenetics reported a “high copy number.” Id. at \*51. Based upon all of the evidence, the Special Master doubted that Unigenetics ever reliably detected the presence of measles virus. Id. If the tests themselves are clearly flawed, the Special Master saw no reason to think that a “strong positive” result is any more trustworthy than a “weak positive” result. Id. Upon careful review, the Court finds the Special Master’s determination reasonable and justified on the record presented. The Court sees no basis to conclude that the Special Master’s treatment of the “high copy numbers” issue is arbitrary, capricious, or an abuse of discretion.

Finally, Petitioners argue that the Special Master ignored evidence from two other laboratories, the Cotter laboratory and the Oldstone laboratory, which allegedly replicated Unigenetics’ test results with respect to high copy numbers. Pet’r Br. 46. Petitioners claim that Dr. Bustin actually provided support for the reliability of Unigenetics testing by comparing its findings with those of the Cotter laboratory, and demonstrating that the two laboratories agreed on the test results for high copy numbers. Id. at 46-47. The Special Master, however, drew no conclusions from these studies because of very limited evidence on this issue. The Special Master observed that “[n]o records of Dr. Cotter’s work, and no testimony or statement from him, have been presented” and therefore “[n]o conclusions can reasonably be drawn.” Cedillo, at \*41. With regard to Dr. Oldstone, the Special Master stated, “[b]ecause Dr. Oldstone himself did not testify, and because his data were not published (for whatever reason), I have not placed any reliance on this item of evidence.” Id. at \*45 n.75.

The Court agrees that, if the work of Dr. Cotter or Dr. Oldstone had any significance, Petitioners should have called them to testify. The Special Master had discretion to decline any conclusions from these studies because of the limited evidence. See Whitecotton v. Sec'y of HHS, 81 F.3d 1099, 1108 (Fed. Cir. 1996) (“Congress desired the special masters to have very wide discretion with respect to the evidence they would consider and the weight to be assigned to that evidence.”).

### 3. Allelic Discrimination

Petitioners have explained “allelic discrimination” as a process used by scientists to ascertain whether a virus is of wild origin or of vaccine-strain origin. Pet'r Br. 49. Citing Exhibit 130, Petitioners assert that the Unigenetics Laboratory used “allelic discrimination” to determine whether the measles virus detected in Michelle Cedillo’s tissue sample was in fact vaccine-strain measles virus. Id. They argue that the Special Master failed to consider the evidence regarding “allelic discrimination.” Id. Petitioners’ imply in their brief that crediting Exhibit 130 would have caused the Special Master to conclude that vaccine-strain measles were detected in Michelle’s tissue sample. See id.

The Special Master included a separate section in the decision explaining the reasons why he did not give any significant weight to Exhibit 130. Cedillo, at \*52-53. Exhibit 130 is a one-page document that Petitioners filed on January 31, 2008, seven months after the conclusion of the evidentiary hearing. Id. at \*52. Apparently, Petitioners did not even present the issue of wild measles versus vaccine-strain measles in their initial post-hearing brief. Id. Exhibit 130 is barely legible, but describes four brief “synopses of papers,” one of which apparently is a reference to the Uhlmann Study. Id. This synopsis indicates use of the technique known as “allelic discrimination.” Id. The Special Master observed that none of Petitioners’ expert witnesses in Cedillo, Snyder, or Hazlehurst even addressed this synopsis or endorsed its accuracy. Id.

The Special Master also noted that, if Exhibit 130 contains a relevant synopsis, Petitioners failed to present the entire referenced article. Id. The synopsis is only a brief summary of a pilot study, with no details provided. Id. Further, if a larger article exists, there is no evidence that the authors submitted the article for scientific peer review and publication. Id. Respondent’s expert, Dr. Rima, did address a “pilot study” in the Snyder hearing, which may have been the same study referenced in Exhibit 130. Id. at \*53. However, Dr. Rima explained that the study did not discriminate accurately between wild measles virus and vaccine-strain measles virus. Id. Petitioners offered no evidence to rebut Dr. Rima’s testimony. Id.

The Special Master concluded that Exhibit 130 did not offer any significant evidence that vaccine-strain measles virus existed in the biologic material of any autistic person. Id. He determined that Petitioners did not demonstrate the existence of measles virus of any type in the body of Michelle Cedillo or of any other autistic child. Id. at \*51. By the Special Master's rejection of the Unigenetics' testing altogether, and his finding of no credible evidence that measles virus existed in any autistic person, the question of whether Unigenetics used "allelic discrimination" to differentiate among measles viruses is a rather meaningless inquiry. The Court finds no error in the Special Master's analysis of "allelic discrimination" or the minimal weight that he ascribed to Exhibit 130. Whitecotton, 81 F.3d at 1108.

#### 4. The Panel of Three Special Masters

Petitioners contend that the use of a panel of three Special Masters to hear the "general causation" evidence in the Cedillo case was arbitrary, capricious, an abuse of discretion, and not in accordance with the law. Pet'r Br. 26-29. Petitioners argue that, when PSC members proposed Cedillo to be heard as the first test case for the OAP, they believed Special Master Hastings was uniquely qualified to hear it because he had considerable experience in handling other test cases under the Vaccine Act. Id. at 27. The PSC objected to the appointment of two additional Special Masters to hear the "general causation" evidence because, "'multiple decisions by multiple Special Masters addressing nearly identical issues of law, fact, science and medicine . . . will generate significant confusion and delay at the appellate level, further slowing progress towards resolving claims in the omnibus.'" Id. at 28 (citing OAP Autism Master File, PSC Reply Br., 2, Feb. 26, 2007). The Cedillos now assert that they had the burden of persuading not one, but three, Special Masters of their causation-in-fact claim. Id. at 28. Petitioners allege that this additional burden violated the fundamental fairness requirement of Vaccine Rule 8. Id. at 29. As explained below, the Court sees no merit to Petitioners' argument.

Vaccine Rule 8 gives the special masters latitude, depending on the circumstances of each case, to determine the format for taking evidence and hearing arguments. See Vaccine Rule 8. Rule 8(b) addresses the concept of fundamental fairness to which Petitioners allude, stating, "[i]n receiving evidence, the special master will not be bound by common law or statutory rules of evidence but must consider all relevant and reliable evidence governed by principles of fundamental fairness to both parties." Id. Vaccine Rule 8 does not prohibit multiple special masters from presiding at an evidentiary hearing.

While it may be true that requiring Petitioners to persuade three special masters of their "general causation" theory would have violated the fundamental fairness provision of Vaccine Rule 8, Petitioners cite nothing in the Special Master's decision or the record to

indicate that they were held to an impermissible burden. To the contrary, while Special Masters Vowell and Campbell-Smith sat on the bench with him during the evidentiary hearing, Special Master Hastings explained that the role of the two additional Special Masters was not to decide *Cedillo*, but to hear the general causation evidence provided by expert witnesses so that they could apply the evidence to the other individual test cases assigned to them. *Cedillo*, at \*10. Special Master Hastings noted, “[w]hile the ‘general causation’ evidence is common to the three cases, each of us has analyzed that common evidence independently of the other two; each has reached his or her own conclusion.” *Id.* at \*11 n.15.

A review of the record and the Special Master’s decision shows that Petitioners were not required to persuade Special Masters Vowell and Campbell-Smith of the merits of their case. The assignment of two additional Special Masters to hear the “general causation” evidence in the test cases, and to assist in deciding some 5,000 autism cases, is an eminently reasonable case management approach. When asked at the oral argument to identify any prejudice from having a three-member panel, Petitioners’ counsel responded, “I don’t know that there was any, Your Honor.” Transcript of Proceedings, 19, July 7, 2009 (“Oral Arg. Tr.”). Petitioners have failed to establish that the presence of three special masters required them to convince anyone beyond Special Master Hastings to prevail in their case, and, therefore, their challenge to the procedures used at the hearing is unavailing.

##### 5. Allowance of Dr. Bustin’s Testimony and Expert Reports

Petitioners contend that the Special Master’s decision shortly before the hearing to allow the expert reports and testimony of Dr. Stephen Bustin was arbitrary, capricious, and an abuse of discretion. Pet’r Br. 29-31. On May 31, 2007, twelve days before the start of the evidentiary hearing, Respondent filed Exhibit UU, an expert report from Dr. Bustin. *Id.* at 29. One week later, on June 7, 2007, Respondent filed two more reports from Dr. Bustin, Exhibits XX and WW. *Id.* These exhibits addressed the reliability of the Unigenetics Laboratory testing. *Id.* at 30. Petitioners claim that they were harmed by having to review these highly technical exhibits and prepare for cross-examination of Dr. Bustin with so little time before the hearing. *Id.* Petitioners assert that, with respect to Exhibits XX and WW, “Michelle’s counsel needed more time to digest the contents of the 123-page highly technical reports.” *Id.*

The exhibits in question are expert reports that Dr. Bustin prepared and filed in the British MMR/autism proceedings during 2003 and 2004.<sup>5</sup> Cedillo, at \*60. The expert reports in the British proceedings are under seal, and may not be divulged without the permission of the British court. Id. at \*35 n.69. Respondent's counsel sought leave of the British court to use Dr. Bustin's expert reports after the filing of Petitioners' expert reports in this case on February 20, 2007. Id. at \*61. At that point, it became clear to Respondent that Petitioners' theory of causation depended upon the validity of the Unigenetics testing. Id. Respondent's counsel received Dr. Bustin's expert reports from the British proceedings on June 7, 2007, and filed Exhibits XX and WW in the Cedillo case within one hour of receiving them. Id. The Special Master found no fault or lack of diligence on Respondent's part in obtaining and filing Dr. Bustin's expert reports. Id.

The Special Master explained that a number of other evidentiary items were filed at a very late stage in these test autism cases, including the reports of Petitioners' experts, Dr. Hepner and Dr. Kennedy, as well as other documents received after the May 25, 2007 deadline for filing exhibits. Id. Typically in Vaccine Act cases, the special masters liberally allow late-filed exhibits, favoring a policy to hear all of the relevant evidence rather than decide a case based upon incomplete evidence. Id. at \*62. In such circumstances, the special masters frequently will allow additional responsive evidence to be filed after the hearing, or they will convene a second hearing where necessary. Id. Special Master Hastings offered these opportunities to Petitioners here. See Evidentiary Ruling, 2, June 8, 2007. Ultimately, Petitioners submitted supplemental expert reports from Dr. Hepner and Dr. Kennedy on October 22, 2007 and November 6, 2007 respectively, but Petitioners did not request a further evidentiary hearing. Cedillo, at \*62.

At the July 7, 2009 oral argument, the Court asked Petitioners' counsel how the Special Master's handling of Dr. Bustin's reports from the British proceedings prejudiced the Cedillos, if at all. Oral Arg. Tr. 21. Petitioners' counsel could not identify any prejudice aside from short-term disruption, explaining that he thought Dr. Bustin was helpful to the Cedillos' case, and admitting, "there was no ultimate prejudice" from Dr. Bustin. Id. at 21, 42.

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<sup>5</sup> Claimants in Great Britain also have asserted that MMR vaccinations cause autism. Sayers v. SmithKline Beecham PLC, [2004] EWHC (QB) 1899. In the British legal system, a government body known as the Legal Services Commission ("LSC") provided funding to claimants to assist in assembling and presenting evidence in support of claims. Cedillo, at \*35 n.69. In September 2003, the LSC ceased funding autism claims because the claimants were not likely to demonstrate that the MMR vaccinations caused autism. Id. (citation omitted). Lacking LSC funding, most autism claimants in Great Britain have not pursued their claims. Id. (citation omitted).

For the reasons addressed above, and described in greater detail in the Special Master's decision, Cedillo, at \*59-65, the Court concludes that the Special Master's admission of Dr. Bustin's testimony and expert reports was reasonable, Petitioners suffered no prejudice therefrom, and the Special Master did not abuse his discretion in this regard. Whitecotton, 81 F.3d at 1108. The Special Master further observed, and the Court agrees, that he would have decided the petition on the merits the same way even if he had disregarded Dr. Bustin's testimony and expert reports. Cedillo, at \*65.

#### 6. Medical Diagnosis of Treating Physicians

Petitioners argue that the Special Master discounted the opinions of Michelle Cedillo's treating physicians, allegedly affording the medical records "absolutely no probative value." Pet'r Br. 32-33. Based upon precedent from the United States Court of Appeals for the Federal Circuit, this Court must give due regard to the medical records of treating physicians. Andreu, 569 F.3d at 1375 ("[T]reating physicians are likely to be in the best position to determine whether a logical sequence of cause and effect show[s] that the vaccination was the reason for the injury.") (quoting Capizzano, 440 F.3d at 1326) (second alteration in original); see also Zatuchni v. Sec'y of HHS, 69 Fed. Cl. 612, 623-24 (2006) (relying upon medical records of treating physicians in concluding that the petitioners had established causation under the Vaccine Act). In this case, Petitioners cite to the medical records of seven treating physicians who allegedly "associated [Michelle's] illness with her MMR vaccine." Pet'r Br. 32.

As the Special Master observed in his decision, most of the medical records of treating physicians merely indicate an awareness of a temporal relationship between the fever Michelle Cedillo experienced after the MMR vaccination and the onset of her autistic symptoms sometime thereafter. Cedillo, at \*128. None of the treating physicians concluded that the MMR vaccine caused Michelle's autism. Petitioners conceded this fact both in their motion for review, Pet'r Br. 32-33, and at oral argument, Oral Arg. Tr. 11. Moreover, none of the treating physicians testified at the hearing. Id. at 12.

A May 2, 1997 letter from an Arizona neurologist, Dr. William Masland, deserves particular mention. Ex. 28 at 207. After examining Michelle Cedillo on May 2, 1997, Dr. Masland noted that Michelle lost her speaking ability after her post-MMR fever episodes. Id. He further stated, "[i]t would appear that there was some neurological harm done at the time of the fevers." Id. He added, "[w]hether this was a post-immunization phenomenon or a separate occurrence, would be very difficult to say." Id.

The Special Master concluded that Dr. Masland's letter, at most, speculated as to whether the MMR vaccine was causing Michelle's neurologic abnormality and did not

constitute an opinion that the MMR vaccine caused Michelle's autism. Cedillo, at \*128. Dr. Masland did not attribute the high fevers to the MMR vaccine, and as the Special Master rightly noted, Michelle had not yet been diagnosed with autism. Id. at \*129. When measured against the array of qualified medical experts who testified unequivocally that the MMR vaccine did not cause Michelle's autism, the Special Master placed little weight on the single-page letter where Dr. Masland simply questioned whether the MMR vaccine, the high fevers, and Michelle's neurologic condition were causally-related. Id. In the words of the Special Master, “[i]t seems astonishing for petitioners to now suggest that Dr. Masland's extremely brief, unexplained speculations contained in his letter of May 2, 1997, should be held to outweigh the opinions of those experts for respondent.” Id.

Once again, Petitioners incorrectly contend that the Special Master afforded the records of the treating physicians “absolutely no probative value.” Pet'r Br. 32. The Special Master devoted a separate section of the decision to the records of the treating physicians. Cedillo, at \*127-29. As the Court finds that the Special Master properly evaluated these records, it will not disturb the Special Master’s conclusions.

#### 7. Alleged “Concessions” of Respondent’s Experts

Petitioners contend that the Special Master failed to consider certain evidentiary “concessions” made by Respondent’s expert witnesses. Pet'r Br. 33-44. Essentially, Petitioners acknowledge that Respondent’s experts are “highly qualified” and “honest scientists who strongly disagree with the conclusions of the petitioners’ experts.” Id. at 33. However, Petitioners assert that the Special Master relied solely upon the number of Respondent’s experts, their exceptional qualifications, and their conclusions, but ignored their evidentiary concessions. Id. at 34. Petitioners state that “the special master found the respondent’s experts’ conclusions *reliable*, but their concessions *unreliable*.” Id. This, they claim, was arbitrary, capricious, and an abuse of discretion. Id.

Petitioners have identified six of Respondent’s expert witnesses whose concessions the Special Master allegedly ignored: Dr. Stephen Bustin, Dr. Bertus Rima, Dr. Diane Griffin, Dr. Brian Ward, Dr. Stephen Hanauer, and Dr. Robert Fujinami. Id. at 34-44. The testimony of Dr. Bustin and Dr. Rima regarding the reliability of the Unigenetics Laboratory testing already has been addressed above.

Contesting the manner in which the Special Master evaluated expert testimony presents an extreme uphill challenge to Petitioners. The Federal Circuit has explained the fact-finding and review process in Vaccine Act cases:

With regard to both fact-findings and fact-based conclusions, the key decision maker in the first instance is the special master. The [Court of Federal Claims] owes these findings and conclusions by the special master great deference – no change may be made absent first a determination that the special master was “arbitrary and capricious.” This is a standard well understood to be the most deferential possible.

Munn, 970 F.2d at 870 (citation omitted); see also Hodges v. Sec'y of HHS, 9 F.3d 958, 961 (Fed. Cir. 1993) (“The statute makes clear that, on review, the Court of Federal Claims is not to second guess the Special Master’s fact-intensive conclusions; the standard of review is uniquely deferential for what is essentially a judicial process.”) (citation omitted). The Federal Circuit also has observed that the abuse of discretion standard “will rarely come into play except where the special master excludes evidence.” Munn, 970 F.2d at 870 n.10.

Upon careful review of the “concessions” cited by Petitioners, the Court finds that Respondent’s expert witnesses indeed agreed with some aspects of Petitioners’ theory of causation. However, in their motion for review, Petitioners simply have woven together as many areas of agreement as possible, and have blindly overlooked the compelling conclusions advanced by Respondent’s experts. A few examples may be instructive.

Petitioners cite a number of “concessions” by Dr. Griffin and Dr. Ward. Pet’r Br. 36-42. Dr. Griffin agreed that a “target organ” of the measles virus is the gastrointestinal tract, id. at 36, and that Michelle Cedillo’s first fever after the MMR vaccination probably was related to the MMR vaccine, id. at 37. Dr. Griffin explained, however, that the second fever a few days later probably was not a result of the MMR vaccine. Cedillo, at \*129 n.203. Dr. Griffin has been studying the measles virus for more than 30 years, and she testified that “[w]e know a lot about what measles virus does when it gets in the brain, and none of it is autism.” Id. at \*68. She also testified that Dr. Kinsbourne’s hypothesis that the measles virus enters the brain and causes autism is not biologically plausible. Id. Similarly, Dr. Ward agreed with some of the points advanced by Petitioners, but his overall conclusions staunchly opposed Petitioners’ theory of causation. As the Special Master noted, “Dr. Ward explained that when measles virus persists in a human brain, death results . . . and any other outcome would be ‘new biology,’ currently unknown to medical science.” Id. at \*69.

Petitioners also rely upon the “concessions” of Dr. Hanauer, Respondent’s expert in gastroenterology. Pet’r Br. 34-36. While Dr. Hanauer agreed that Michelle Cedillo has significant bowel symptoms, and he conceded that diarrhea frequently follows a measles vaccination, id. at 35, his overall conclusions were decidedly adverse to Petitioners. As noted by the Special Master, Dr. Hanauer, “disagrees completely with Dr. Krigsman’s

*general opinion* that the MMR vaccine can cause chronic gastrointestinal dysfunction by persisting in a child's body." Cedillo, at \*104. Dr. Hanauer was "unaware of *any* examples of viral persistence in intestinal tissue causing *chronic* inflammation." Id. at \*109.

Dr. Fujinami co-authored an article with Dr. Oldstone entitled *Virus Persistence and Avoidance of Immune Surveillance: How measles viruses can be induced to persist in cells, escape immune assault, and injure tissues*, 33<sup>rd</sup> Symposium of the Society for General Microbiology, at 185-202 (Mar. 1982). The Special Master admitted this article into evidence, Ex. 132, but neither Dr. Fujinami nor Dr. Oldstone testified. Petitioners complain that the Special Master denied them the opportunity to cross-examine Dr. Fujinami about his report. Pet'r Br. 42. Petitioners state that Dr. Fujinami, "has known for decades . . . that measles virus can persist in human cells, injure tissues, and cause a potentially damaging autoimmune response." Id. (emphasis omitted). Simply put, if Petitioners wanted this information to support their theory of causation, they should have called Dr. Fujinami, or Dr. Oldstone, as witnesses.

This is not a case where the Special Master declined to consider important evidence, or failed to admit relevant exhibits or testimony. To the contrary, the Special Master thoroughly considered every viewpoint of every expert witness, both Petitioners' and Respondent's, and concluded that the evidence was "overwhelmingly" in Respondent's favor. Cedillo, at \*1. This Court will not second guess a Special Master's fact-intensive conclusions, especially when medical evidence of causation is in dispute. Hodges, 9 F.3d at 961 (citation omitted); Moberly v. Sec'y of HHS, 85 Fed. Cl. 571, 597 (2009) (citation omitted).

#### 8. Alleged "Ignoring" of Petitioners' Other Evidence

Petitioners have identified seven substantive areas where the Special Master allegedly "ignored" important aspects of the evidence concerning: (1) the reliability of the Unigenetics Laboratory test results, particularly as to "high copy numbers;" (2) allelic discrimination; (3) persistent measles virus and replication; (4) Dr. Krigsman's diagnosis; (5) neuroinflammation; (6) Michelle Cedillo's immune system; and (7) mercury and immune system dysfunction. Pet'r Br. 45-63. The Court already has addressed items one and two above, as they relate to the pivotal issue of the reliability of the Unigenetics testing. The Court will discuss the remaining items below.

##### a. Persistent Measles Virus and Replication

Petitioners argue that the Special Master ignored evidence from an article co-authored by Respondent's expert virologist, Dr. Griffin, regarding replication of the measles virus.

Dr. Griffin testified that the presence of measles virus in Michelle Cedillo's tissue sample, even if true, did not indicate disease because the virus could not replicate without protein. Pet'r Br. 50. However, Petitioners assert that the Special Master ignored an allegedly conflicting article of Dr. Griffin's stating that measles virus samples from other patients were persistent and replicating, even in the absence of protein. Id. (citing Ex. 112, Tab L). Petitioners rely upon this article to support their contention that the measles virus found in Michelle's gut tissue was not inert, but was multiplying and causing harm. Id. at 50-51.

As Respondent points out, Petitioners' counsel did not ask Dr. Griffin about this article during cross-examination, despite the opportunity to do so, and none of Petitioners' expert witnesses relied upon this article. Resp't Br. 38-39. Petitioners' claim that measles virus can persist and replicate without protein, therefore, represents nothing more than their counsel's interpretation of the Griffin article. Id. To the extent that Petitioners offered this contention to support the reliability of the Unigenetics testing, the Special Master correctly disregarded Dr. Griffin's article when no medical expert offered any testimony concerning its proper interpretation, and the great weight of the evidence contradicted it. The Court does not see any abuse of discretion by the Special Master regarding his treatment of Dr. Griffin's article.

#### b. Dr. Krigsman's Diagnosis

Petitioners challenge the Special Master's assessment of Dr. Krigsman, their expert in gastroenterology. Petitioners allege that the Special Master "reserved special venom" for Dr. Krigsman and failed to evaluate his diagnosis of Michelle, while crediting instead the testimony of Respondent's expert, Dr. Hanauer. Pet'r Br. 51-55.

Contrary to Petitioners' assertion, the Special Master analyzed Dr. Krigsman's testimony in great detail, and found it unconvincing. Cedillo, at \*29, 33, 47, 79, 103-112, 114-127, 133, 135. Dr. Krigsman testified that Michelle Cedillo has inflammatory bowel disease, which the MMR vaccination caused. Id. at \*103-04. The Special Master rejected this view:

I conclude that [Michelle's medical] records do not indicate that any physician other than Dr. Krigsman actually *independently diagnosed* Michelle with intestinal inflammation, or any *chronic* inflammation anywhere in her gastrointestinal tract. And I find that Dr. Krigsman was not a credible witness, so that his own diagnosis in that regard is not reliable.

Id. at \*124. The Special Master noted that Dr. Krigsman diagnosed Michelle with inflammatory bowel disease in July 2003, before he ever met or examined her. Id. at \*112 n.180. He also observed that Petitioners never offered any rebuttal testimony to Dr. Hanauer's criticisms of Dr. Krigsman's opinion. Id. at \*125 n.198.

The Special Master offered three chief reasons why Dr. Krigsman's opinion should be rejected. First, Dr. Krigsman relied upon the discredited Unigenetics testing in forming his opinion. Id. at \*114. Second, the Special Master determined that Dr. Krigsman had a "*grossly mistaken* understanding of the history of Michelle's gastrointestinal symptoms," and that his testimony was inconsistent with Michelle's medical records. Id. Third, he found Dr. Krigsman's conclusion that Michelle suffered from chronic gastrointestinal inflammation to be "substantially outweighed by a combination of the medical records and the testimony of respondent's experts, especially Dr. Hanauer." Id. at \*115.

Under the Vaccine Act, "[s]pecial masters are accorded great deference in determining the credibility and reliability of expert witnesses." Nilson v. Sec'y of HHS, 69 Fed. Cl. 678, 681 (2006) (citing Hanlon v. Sec'y of HHS, 191 F.3d 1344, 1349 (Fed. Cir. 1999)); see also Hampsch v. Dep't of Treasury, 796 F.2d 430, 436 (Fed. Cir. 1986) (findings regarding the credibility of witnesses are "virtually unreviewable" given the opportunity of trial judges to examine the witnesses). The Court will not second-guess the Special Master's analysis and credibility assessments of Dr. Hanauer or Dr. Krigsman. See Hodges, 9 F.3d at 961; Moberly, 85 Fed. Cl. at 597.

### c. Neuroinflammation

Petitioners assert that chapters from a text edited by Dr. Andrew Zimmerman, one of Respondent's expert pediatric neurologists, support the theory that neuroinflammation causes autism. Pet'r Br. 57. Petitioners further contend that persistent measles infection has resulted in two recognized brain disorders, subacute sclerosing panencephalitis ("SSPE") and measles inclusion body encephalitis ("MIBE"). Id. at 56. Petitioners argue that the Special Master failed to account for relevant evidence linking the measles virus to these brain disorders. Id. at 56-57. The Special Master noted, and Respondent's experts did not deny, that inflammation may exist in the brains of autistic persons, and may possibly play a causal role in autism. Cedillo, at \*69 n.109. However, the Special Master rejected the proposition that vaccine-strain measles virus plays any role in causing brain inflammation in autistic persons. Id.

Petitioners first submitted the materials edited by Dr. Zimmerman with their March 13, 2009 motion for reconsideration, which the Special Master ruled they filed untimely. See infra § C(9). However, the Special Master did not ignore relevant evidence, but weighed it

against evidence presented by Respondent that he ultimately found more credible. Cedillo, at \*65-71. In rejecting Petitioners' general theory that measles virus contributes to autism, the Special Master identified nine points to support his analysis, one of which was that "the available evidence still does not demonstrate that measles virus persistence in the brain would result in *autism*." Id. at \*67.

The Special Master acknowledged the testimony of Petitioners' expert, Dr. Marcel Kinsbourne, that persistent measles virus in the human brain might cause a different disorder besides SSPE or MIBE. Id. at \*69. The Special Master explained, however, that Dr. Kinsbourne "supplied no *evidence* for such a possibility, beyond his own unsubstantiated speculation." Id. Conversely, the Special Master found Respondent's experts "to be much more credible and persuasive." Id. Respondent's experts, Dr. Griffin, Dr. Ward, and Dr. Wiznitzer, testified that a chronic infection of the brain such as SSPE or MIBE would result in a person's death, rather than autism or inflammation. Id. at 68-69. Dr. Wiznitzer opined that Dr. Kinsbourne's theory would require a "novel biologic model," for which no evidence exists. Id. at 69.

Once again, the Court will not second-guess the Special Master's reasoned analysis of expert testimony. See Hedges, 9 F.3d at 961; Moberly, 85 Fed. Cl. at 597. The evidence on neuroinflammation supports the Special Master's conclusion that Respondent's experts presented a far more compelling position, and were much better qualified, than Petitioners' experts. The Special Master carefully examined every position advanced by the parties in his undeniably thorough decision. The Court rejects Petitioners' assertion that the Special Master's determination was arbitrary, capricious, or an abuse of discretion. See Hanlon, 191 F.3d at 1349 (finding that a special master's determination was not arbitrary, capricious, or an abuse of discretion, and was in accordance with the law when there was ample support for it in the record).

#### d. Michelle Cedillo's Immune System

Petitioners challenge the Special Master's determination that Michelle Cedillo does not have a damaged immune system. See Pet'r Br. 59-60. Specifically, Petitioners contend that the Special Master abused his discretion by favoring Respondent's expert, Dr. Christine McCusker, over Petitioners' expert, Dr. Vera Byers. See id. Petitioners mainly attack Dr. McCusker's alleged use of a "fabricated pediatric lab value range" to show that Michelle's immune system was normal. Id. at 59. The Special Master observed, however, that Dr. McCusker referred to "a published set of *age-adjusted* normal values developed in testing of children." Cedillo, at \*27. Using this approach, Dr. McCusker determined that Michelle had a normal immune system. Id. The Special Master found that Dr. McCusker was "far more persuasive" than Dr. Byers, and was satisfied that age-appropriate values should be

used when evaluating immune testing results of children. Id. The Special Master provided a full and careful analysis of these experts' testimony and their qualifications, and concluded Petitioners failed to demonstrate that thimerosal damaged Michelle's immune system. Id. at \*25-29. The Court sees no basis for disturbing the Special Master's evaluation of these expert witnesses.

#### e. Mercury and Immune System Dysfunction

Petitioners allege the Special Master ignored relevant evidence regarding the effects of mercury on Michelle Cedillo's immune system. Pet'r Br. 60-63. They claim that Michelle's weakened immune system allowed the measles virus to persist long after it should have eliminated the virus from her body. Id. Petitioners assert that the Special Master "ignored the entire body of literature that [Respondent's expert,] Dr. Brent[,] alluded to in his testimony" demonstrating that mercury "had a detrimental effect on all elements of the immune system." Id. at 62.

As the Special Master explained, Dr. Brent did not dispute that mercury in some of its forms and at certain dosages can be toxic or fatal to humans. Cedillo, at \*18. Dr. Brent emphasized, however, that Petitioners' expert, Dr. Aposhian, inappropriately relied upon instances of toxicity involving mercury in much different forms than are found in thimerosal, and mercury exposure in much greater amounts than the small quantities used as preservatives in vaccines. Id.

Dr. Brent also explained that thimerosal breaks into component parts as soon as it enters the body, releasing mercury in the form of "ethyl mercury." Id. According to Dr. Brent, the toxic properties of ethyl mercury are quite different from methyl mercury, and Dr. Aposhian improperly relied upon the "reference dose" standards of methyl mercury, instead of the ethyl mercury in thimerosal. Id. The Special Master accepted Dr. Brent's testimony that the type of mercury (ethyl or methyl) and the dosage amount are the most important factors in determining whether an adverse effect will occur. Id. The examples of Dr. Aposhian's cited mercury toxicity levels involve vastly greater amounts of mercury than are used in thimerosal. Id. Dr. Brent pointed out that almost any substance can be toxic if administered in high enough quantities, but that the same substance can be harmless or beneficial at low doses. Id.

Based upon all of the expert testimony, the Special Master found no evidence that the amount of ethyl mercury in thimerosal causes any immune dysfunction. Id. The record supports this determination. Furthermore, the Special Master provided sufficient reasoning in his decision for his acceptance of Dr. Brent's expert analysis instead of Dr. Aposhian's.

Id. Upon careful review, the Court will not disturb these conclusions. See Hanlon, 191 F.3d at 1349.

#### 9. Refusal to Consider Post-Hearing Evidence

Petitioners challenge the dismissal of their motion for reconsideration, contending that the Special Master abused his discretion by refusing to consider significant post-hearing evidence. Pet'r Br. 63-65. Petitioners filed their motion for reconsideration with the Special Master on March 13, 2009, just three days before a motion for review would have been due in this Court.

Motions for reconsideration are governed by Vaccine Rule 10(e), which provides in part:

(1) ***Initial Motion.*** Either party may file a motion for reconsideration of the special master's decision within 21 days after the issuance of the decision, if a judgment has not been entered and no motion for review under Vaccine Rule 23 has been filed.

(2) ***Response.*** The special master may seek a response from the nonmoving party, specifying both the method of and the timing for the response.

(3) ***Ruling on the Motion.*** The special master has the discretion to grant or deny the motion, in the interest of justice.

Vaccine Rule 10(e)(1)-(3). Here, the 21-day period for filing a motion for reconsideration expired on March 5, 2009. Petitioners offered no explanation for filing their motion outside of the 21-day time period. Cedillo, 2009 WL 996299, at \*1 n.1. As the Special Master speculated, by filing on March 13, 2009, Petitioners seemingly positioned the motion for a prompt ruling from the Special Master without an opportunity for Respondent to answer. Id.

The materials Petitioners submitted with their motion for reconsideration consisted of: (1) chapters from a book edited by one of Respondent's experts, Dr. Andrew Zimmerman; (2) medical articles published in September 2008 and March 2009; (3) an affidavit from Petitioners' expert, Dr. Kennedy, rebutting testimony of Respondent's expert, Dr. Rima; and (4) additional medical records of Michelle Cedillo. Exs. 134-38. The Special Master denied Petitioners' motion as untimely, and held that he would not have considered Petitioners' evidence even if they had timely filed it. Cedillo, 2009 WL 996299, at \*1. He observed that, with the exception of one medical journal article which he found "of very dubious

relevance,” every new piece of evidence was available “prior to the *filings of my Decision* in this case on February 12, 2009.” Id. He also noted that “*none* of those evidentiary items constitute[s] evidence that *vaccines* can cause autism or gastrointestinal dysfunction.” Id.

The Court finds that the Special Master acted well within his discretion in denying Petitioners’ motion for reconsideration. Petitioners did not timely file their motion under Vaccine Rule 10(e), and the Special Master properly determined that there was no reason “in the interest of justice” to consider the evidence proffered with the motion.

#### 10. Whether the Special Master’s Decision is Contrary to Law

Petitioners assert essentially three arguments that the Special Master improperly applied the law: (a) he employed Daubert v. Merrell Dow Pharmaceuticals, Inc., 509 U.S. 579 (1993) “as a clout to dismiss [this] petition,” Pet’r Br. 70; (b) he misapplied the causation requirements of Althen, 418 F.3d at 1278; and (c) he disregarded Court precedent granting relief to other petitioners, particularly where the MMR vaccine caused injury, based on evidence allegedly similar to or less compelling than the evidence presented here. Each of these contentions is addressed below.

##### a. The Special Master’s Use of Daubert

Petitioners first argue that the Special Master improperly applied Daubert in evaluating the reliability of their expert testimony and other scientific evidence. In Daubert, the Supreme Court set forth four factors for determining the admissibility of scientific evidence at trial. Daubert, 509 U.S. at 593-94. These factors are (1) general acceptance in the scientific community, (2) whether the theory has been subjected to peer review and publication, (3) whether it can and has been tested, and (4) whether the known potential rate of error is acceptable. Id. According to Petitioners, courts may only use the Daubert factors to assess expert witnesses’ methodology and not their ultimate conclusions. Pet’r Br. 65. Therefore, the Special Master acted contrary to the law in applying Daubert to assess the reliability of Petitioners’ expert witnesses and other scientific evidence. Id.

Federal Circuit precedent clearly permits the Special Master to apply Daubert when evaluating the reliability of the parties’ evidence. In Terran v. Secretary of Health and Human Services, the Court of Federal Claims concluded that “Daubert is useful in providing a framework for evaluating the *reliability* of scientific evidence,” both under the Federal Rules of Evidence and in Vaccine Act cases. 41 Fed. Cl. 330, 336 (1998) (emphasis added) (citation omitted), aff’d, 195 F.3d 1302 (Fed. Cir. 1999). In affirming this decision, the Federal Circuit found reasonable the trial court’s application of Daubert to assess the reliability of an expert witness. Terran, 195 F.3d at 1316. Furthermore, the Supreme Court

has clarified language in Daubert stating that the focus of a Daubert inquiry must be “solely on principles and methodology, not on the conclusions that they generate” by acknowledging that “conclusions and methodology are not entirely distinct from one another . . . . A court may conclude that there is simply too great an analytical gap between the data and the opinion proffered.” Gen. Elec. Co. v. Joiner, 522 U.S. 136, 146 (1997) (quoting Daubert, 509 U.S. at 595).

Here, the Special Master concluded that “another important aspect of the causation-in-fact law under the [Vaccine] Program concerns the factors that a special master should consider in evaluating the *reliability* of expert testimony and other scientific evidence relating to causation issues.” Cedillo, at \*3. He then referenced the Daubert factors “that federal trial courts should utilize in evaluating proposed expert testimony concerning scientific issues.” Id. In applying Daubert, the Special Master simply found that the evidence did not support the conclusions proffered by Petitioners’ experts. Id. at \*135. The Special Master had the discretion under Terran to apply Daubert when assessing the conclusions of the parties’ expert witnesses, and, therefore, he did not act contrary to law.

#### b. The Althen Causation Standard

Petitioners also contend that the Special Master improperly applied the Althen test in evaluating whether Petitioners had met their burden of proof. Under Althen’s causation standard, the petitioner has the burden of proving by a preponderance of the evidence: (1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a proximate temporal relationship between vaccination and injury. 418 F.3d at 1278. Petitioners claim they have met their burden of proof, and the Special Master’s conclusion to the contrary demonstrates his failure to apply Althen correctly. They argue that they presented a medical theory because “[the] evidence is overwhelming that the MMR vaccine is capable of causing a wide variety of brain injuries, including autism.” Pet’r Br. 68. Furthermore, Petitioners maintain that they offered a logical sequence of cause and effect between the MMR vaccine and Michelle’s injury: she had been healthy, she received the MMR vaccine, and “she was never again the same.” Id. Finally, Petitioners assert that they met the proximate temporal relationship prong of the test because Michelle’s symptoms occurred within the fifteen days required for proving that a brain injury resulted from the MMR vaccine under the Vaccine Injury Table. Id.; 42 U.S.C. § 300aa-14(a)II. Confronted with this evidence, Petitioners argue that the Special Master could not have found in Respondent’s favor unless he had elevated the causation standard beyond what Althen requires.

The Special Master properly concluded that Petitioners failed to meet any of the three prongs of the Althen test.<sup>6</sup> Althen mandates that a claimant offer a “*persuasive* medical theory,” supported by reputable medical or scientific explanation. 418 F.3d at 1278 (emphasis added). The Special Master determined that Petitioners failed to offer a reliable medical theory as to how the MMR vaccine can cause autism or inflammatory bowel disease, and that any such theories were highly speculative. See, e.g., Cedillo, at \*21-22, 26-27, 41, 58, 89-90, 96, 101, 108. Absent proof of a persuasive medical theory, the Special Master did not act contrary to law in concluding that Petitioners failed to meet the first prong of Althen.

Under the second prong of the test, Petitioners’ sequence of cause and effect depends upon a presence of persistent measles virus infection in Michelle’s body. However, the Special Master concluded that “the petitioners offered *virtually no evidence* concerning this necessary element in their proposed chain of proof—*i.e.*, their claim that the measles virus, which they claim to persist in [autistic] children, is *vaccine-strain* measles virus.” Id. at \*52. The Special Master also saw no logical sequence of cause and effect between the MMR vaccine and Michelle’s development of inflammatory bowel disease. Specifically, the Special Master found Dr. Krigsman’s theory that Michelle suffered from an MMR-induced inflammatory bowel disease to be factually incorrect because Michelle did not suffer from gastrointestinal inflammation, and Dr. Krigsman “gravely misunderstood the temporal history of Michelle’s gastrointestinal problems.” Id. at \*114-15. The Special Master’s conclusion that Petitioners failed to demonstrate any relationship between the MMR vaccine and Michelle’s autism is eminently reasonable. He determined that they offered “*virtually no evidence*” to support their claim. See id. at \*52.

The Special Master also correctly noted that the onset of an injury following a vaccination alone does not satisfy the third prong of the Althen test. See id. at \*132-33. Petitioners must establish a proximate and scientific temporal relationship between vaccine and injury. Pafford v. Sec’y of HHS, 64 Fed. Cl. 19, 29-31 (2005), aff’d, 451 F.3d 1352 (Fed. Cir. 2006). Petitioners claim that Michelle first showed symptoms of autism within a few days of receiving her December 20, 1995 MMR vaccination. Pet’r Br. 68. However, the Special Master found no evidence to support this allegation, stating that “[t]he medical records and testimony . . . contradict Dr. Kinsbourne’s assumption that Michelle experienced an abrupt onset of autism symptoms” shortly after her MMR vaccination, and that Michelle’s overall record demonstrated that her family “noticed symptoms of [her] autism *gradually*.” Cedillo, at \*99, 101. Furthermore, Dr. Kinsbourne admitted that he “really doesn’t know what would be the [biologically] appropriate time period for onset of an autism condition

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<sup>6</sup> Petitioners argue that they should prevail because Respondent failed to prove an alternative cause of Michelle’s autism. Petr. Br. 68-70. However, the burden of proof does not shift to Respondent until Petitioners succeed in establishing a *prima facie* case. Knudsen, 35 F.3d at 547 (citation omitted). The Court has concluded that the Special Master properly applied the Althen test to determine that Petitioners had not met their burden of proof. Because no burden shift has occurred, the Court need not address Petitioners’ argument.

caused by the MMR vaccination” and was, therefore, “merely *guessing or speculating.*” Id. at \*137. As to Michelle’s chronic gastrointestinal symptoms, Dr. Krigsman never offered a biologically appropriate temporal relationship and was “*completely wrong* in his assumption as to when Michelle’s chronic gastrointestinal symptoms *actually did begin.*” Id. at \*133. The Special Master provided substantial evidentiary support for his conclusion that Petitioners failed to show, by a preponderance of the evidence, a scientific temporal relationship between the MMR vaccine and Michelle’s autism or gastrointestinal problems. There is no evidence to support Petitioners’ claim that the Special Master elevated the burden of proof set forth in Althen.

### c. Other Cases Finding Injury From the MMR Vaccine

Finally, Petitioners allege that the Special Master disregarded precedent in which the Court granted relief to petitioners, particularly where the MMR vaccine caused injury, based on evidence allegedly similar to or less compelling than the evidence presented here. Petitioners point to a list of cases in which medical records, affidavits, expert testimony, and scientific articles, all based on circumstantial evidence alone, established that vaccines have caused certain injuries. Pet’r Br. 11-14. They argue that, in each of these cases, as in Michelle’s case, the respondent’s experts flatly denied that a vaccine was capable of causing the injury, and yet the Court awarded relief. Id. at 14. According to Petitioners, the Court correctly decided these cases because the Althen test permits petitioners to establish a *prima facie* case based on circumstantial, rather than direct scientific, evidence, and a special master must resolve “close calls regarding causation . . . in favor of injured claimants.” Althen, 418 F.3d at 1278; see also Cappizano, 440 F.3d at 1326. Petitioners contend that the purpose of this standard is to “allow the finding of causation in a field bereft of complete and direct proof [as to] how vaccines affect the human body.” Althen, 418 F.3d at 1280.

The Special Master did not improperly apply the law in declining to consider the Vaccine Act decisions Petitioners reference. The Special Master explicitly rejected Petitioners’ argument for faulty logic, noting that Petitioners failed to mention the thousands of other cases in which special masters have denied relief for failure to prove by a preponderance of the evidence that a vaccine caused an injury. Cedillo, at \*130. Furthermore, he concluded that Michelle’s case bears no resemblance to those cited by Petitioners: “In this case, the petitioners have advanced a theory of causation quite unlike any causation theory that I have previously seen in the 20 years of the Program’s history. I have carefully evaluated that theory. Based upon all the evidence, I have found that theory to be without merit.” Id. The Court finds no legal error in the Special Master’s determination that these cases are factually distinct from the case at hand. Unlike the medical issues raised in other Vaccine Act cases, autism is not an area ““bereft of complete proof.”” Pet’r Br. 66 (quoting Althen, 418 F.3d at 1280). As the Special Master explained in his decision, scientists have performed numerous, reputable epidemiological studies worldwide that have attempted, and failed, to detect an association between childhood vaccinations and autism.

Cedillo, at \*1, 84-93. Furthermore, Petitioners have again mischaracterized the law under Althen. While a special master must resolve “close calls” in favor of a petitioner, Special Master Hastings concluded that this “is *not a close case*;” rather, “[t]he overall weight of the evidence is *overwhelmingly contrary* to the petitioners’ causation theories.” Id. at \*134. Petitioners still have the burden of proving their claims by a preponderance of the evidence, and the Special Master reasonably concluded that they failed to do so. Accordingly, Petitioners’ argument that the Special Master’s decision was not in accordance with the law is without merit.

### Conclusion

The issue before our Court is not to determine the causes of autism. The Court can only hope that medical professionals succeed in identifying the causes and developing a cure for this tragic disease. Rather, the Court’s task is to weigh the Special Master’s February 12, 2009 decision under the applicable review standards of the Vaccine Act, and determine whether it should affirm or modify the decision to any extent. After performing this review, the Court is satisfied that the Special Master’s decision is rational and reasonable in all respects, and is in accordance with law. For the reasons addressed above, the Special Master’s decision is AFFIRMED.

IT IS SO ORDERED.

s/ Thomas C. Wheeler  
THOMAS C. WHEELER  
Judge